

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

IN RE PET FOOD PRODUCTS : MDL Docket No. 1850 (All Cases)  
LIABILITY LITIGATION :  
: Case No. 07-2867 (NLH)  
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**DECLARATION OF DR. GEORGE  
MCCABE IN SUPPORT OF  
DEFENDANTS' RETRIEVAL  
PLANS FOR ORGANIZED  
RECALLED PRODUCT**  
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STATE OF INDIANA )  
COUNTY OF TIPPECANOE ) SS:  
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Dr. George P. McCabe affirms the following under penalty of perjury:

1. I am currently Professor of Statistics at Purdue University, and a Fellow of the American Statistical Association. I received a B.S. in Mathematics from Providence College and a Ph.D. in Mathematical Statistics from Columbia University. I have continuously taught statistics at Purdue University from 1970 until the present day. I have authored three textbooks and one hundred fifty seven articles on issues related to statistics. Among other courses, I have taught sampling and sampling techniques at the graduate and undergraduate level. A copy of my curriculum vitae is Attachment A to my Declaration filed December 11, 2007 in support of Defendants' Unopposed Motion to Limit the Retention of Organized Product, Raw Wheat Gluten and Unorganized Inventory ("Preservation Motion").

2. I was retained by several Defendants, including The Iams Company ("Iams"); Hill's Pet Nutrition ("Hill's"); Nutro Products, Inc. ("Nutro"); Nestle Purina PetCare Company ("Purina"); Del Monte Foods Company ("Del Monte"); Menu Foods, Inc.; Menu

**Exhibit A to  
Retrieval Motion**

Foods Income Fund; Menu Foods GenPar Limited; Menu Foods Holdings, Inc.; Menu Foods Limited; Menu Foods Limited Partnership; Menu Foods Midwest Corporation.; Menu Foods Operating Limited Partnership; Menu Foods South Dakota, Inc.; Menu Foods Operating Trust; and Menu Foods Acquisitions Inc. (collectively, "Menu Foods"); and ChemNutra Inc. ("ChemNutra"), to identify a "sampling plan" for certain recalled product stored by Defendants. I understand that these Defendants filed an unopposed motion, the Preservation Motion, on December 11, 2007, asking the Court to adopt my sampling plan set forth in a Declaration attached to the Preservation Motion as Exhibit 10 (referred to here as "12/11/07 Declaration" or "Sampling Plan").

3. The stated purpose of the Sampling Plan is "[(1)] . . . to preserve certain products which will later be tested to determine the percent of contamination, if any, in the original populations . . . [(2)] to ensure that test results on the samples, when analyzed by a statistician, will enable accurate inferences to be drawn about the distribution of the percent of contamination in the original populations . . . and [(3)] to answer the statistical question -- how much product does each Defendant need to retain in order for the parties and the Court to have a sufficient sample that is representative of the whole in a statistically significant manner." Id. ¶ 2.

4. I understand the Court granted Defendants' Preservation Motion to implement my proposed Sampling Plan on December 18, 2007 ("12/18/07 Order"). The Sampling Plan recommends that each Defendant retain 500 units (*i.e.*, individual cans or pouches) per SKU date, 500 samples per batch number of raw wheat gluten, and 500 samples per recipe of the work-in-progress. 12/11/07 Declaration, ¶ 11.

5. Defendants have now requested that I prepare individual retrieval plans to enable each Defendant to implement Judge Hillman's 12/18/07 Order. The retrieval plans direct each Defendant to collect specific units or samples from each SKU date or batch of raw product. The retrieval plans are designed to ensure the goals of the Sampling Plan -- i.e., to preserve a sample of products that, when later tested and analyzed by a statistician, will enable accurate inferences to be drawn about the distribution of the percent of contamination, if any, in the original population in a statistically significant manner. In other words, the goal of the retrieval plans is to sample product in such a way that 500 units or samples, that are statistically representative of the product corresponding to each SKU date or batch of raw wheat gluten, will be preserved for future testing. I understand the remaining product not selected for sampling will be discarded.

6. To prepare the retrieval plans, I requested and obtained from each Defendant its records identifying the stored recalled product with SKU date, pallet identification numbers, the number of cases per pallet, the number of units per case and the quantity of product per SKU date. This Declaration addresses the Organized Recalled Product only; it does not address the retrieval plans for the raw wheat gluten or work-in-progress.

7. To prepare the retrieval plans, I also interviewed key personnel with knowledge of the production processes from Menu Foods, Purina, Del Monte, Hill's and Iams. Specifically, I interviewed Chris Mifflin, Menu Foods Executive Vice President of Operations, and Steve Lindsay, Menu Foods Plant Manager and Vice President of Operations. Messrs. Mifflin and Lindsay answered my questions regarding Menu Foods' production processes and the variability of product per SKU date. I interviewed Adrian Palenski, Purina's Director of Quality Assurance, who answered similar process and variability questions for Purina. I also

interviewed Tom Robinson, the Regional Category Quality Assurance Leader for Iams in September 2007 and January 29, 2008. Mr. Robinson answered my questions about customer expectations of product uniformity and the time commitment of breaking down each pallet as part of any retrieval plan. I also spoke with Michael Hayes, Director of Quality Assurance for Del Monte about its production processes. Finally, I spoke with Wes Barricklow, Hill's Director of Product Development, formerly the Director of Supply Chain Integration for Hill's, about customer expectations of product uniformity and processes, and Hill's product stored in bags, not cases, and palletized. These interviews were in addition to those conducted last fall of each Defendant in preparation of the Sampling Plan.

8. As a result of my interviews, I have the following understanding of aspects of the production process relevant to the retrieval plans. First, an SKU date represents all product of a particular type (or recipe) that is produced in a given production run. The product is produced in batches. Typically, there are 2 to 6 batches per SKU date, but the number of batches can range from 1 to 20 per SKU date. The raw material for each batch is thoroughly mixed and then extruded and placed into units. Units are either cans or pouches. The units are heated in what is known as a "retort" to achieve commercial sterility and then placed into cases. Typically there are 12 or 24 units per case. Cases are then immediately placed onto pallets. Typically, there are 112 to 220 cases per pallet with the larger number of cases per pallet being associated with a smaller number of units per case.

Second, the production process is sequential and continuous. A long stream of units is produced that are placed into cases sequentially in the order that they came out of the retort and the cases are placed onto pallets in sequential order. The last case placed onto the top of one pallet typically will contain units that came out of the retort immediately before the units

in the first case placed onto the bottom of the next pallet. The key point here is that the product produced from an individual batch will fill many pallets.

Third, the entire production process is designed to provide high quality pet foods to customers. In statistical terms, high quality means that there is no variation from unit to unit for the same item and variation from batch to batch is very small, i.e., 0.5% or less. The production process is designed for uniform production. Repeatability is a key aspect of the production process and quality assurance mechanisms ensure uniformity.

Fourth, the process of putting product into units, cases, and pallets is very fast. A case is filled in seconds and a pallet will typically be filled in 3 to 6 minutes. For example, for 3-ounce cans, Menu Foods fills 1,000 cans per minute and 11.5 pallets per hour; for 13.2-ounce cans, it fills about 700 cans per minute and 21 pallets per hour, etc.

9. Based upon communications with Mr. Hayes, Del Monte's production processes are similar to those of Menu Foods and Purina. While Del Monte typically produces more batches per SKU date, each batch fills many pallets, the process is very fast, sequential and continuous, and the processes are designed for uniform production. Based on the production process as described above -- especially that (a) thoroughly mixed raw ingredients are extruded to rapidly fill cases and pallets, (b) the process of filling cases and pallets is continuous and sequential, (c) multiple pallets are filled from each batch, and (d) the production process is designed to ensure uniformity within batches and minimize variability between batches -- we expect any variation, though small, to be between batches, not within batches. Accordingly, the retrieval plans will capture any batch-to-batch variation by focusing on pallets.

10. Since Defendants have stated that it is more convenient for them to select and store product in intact cases rather than individual cans or pouches at this point in time, the plan specifies the cases to be selected. From the selected cases, the same number of cans or pouches will be sampled from each case in such a way that the total number of units retained is at least 500 per SKU date.

11. The general format of the retrieval plans for each Defendant provides that the Defendant will retrieve at least one case per pallet. In general, for SKU dates with 26 or more pallets, one case will be retrieved per pallet and for SKU dates with 1 to 25 pallets, two cases per pallet will be selected where more than 500 units are available. Where 500 or fewer units exist on an SKU date, all units will be retained. Also, if one or more pallets have only one case, or if the total number of units in the initial selection of cases is less than 500 for any reason, additional cases will be selected from pallets to meet the goal of 500 units. This will be done in such a way that equal numbers of cases will be selected from pallets with a sufficient number to do this and all cases will be selected from pallets with fewer cases. The algorithms that implement these selection procedures are contained in the computer programs used for each Defendant, attached as Appendix A to this Declaration.

12. Another way of describing the plan is to first think about the number of pallets for a particular SKU date. If we know the number of pallets and the number of units per case for the SKU date, we can determine the number of units retrieved when we take one case per pallet. If this number of units is 500 or more, then one case per pallet will be sufficient and this is what the plan specifies for the SKU date. If the number of units is 499 or less, consider taking 2 cases per pallet. Again, calculate the number of units that would be selected with this choice and determine if it is 500 or more. If not, consider 3 cases per pallet and so forth.

13. The following examples are from the Menu Foods data file. We consider first an SKU date with a small number of pallets and then an SKU date with a large number of pallets.

Consider an SKU date with 3077 pouches of a 5.5-ounce product with 24 pouches per case. The total number of cases is  $3077/24=128.2$ , which we round down to 128. For this product there are 126 cases per pallet, so there are  $128/126=1.02$  pallets, which we round down to 1. The retrieval plan states that 21 cases will be retained per pallet. If the 128 cases are on one full pallet with 126 cases and the remaining 2 cases are on another pallet, we will select 21 cases from the full pallet and 2 from the partial pallet. The number of cases to be selected per pallet is based on the rounded number of pallets and the number of units per case. Since there are  $21 \text{ cases} \times 24 \text{ pouches} = 504$  pouches to be selected from the full pallet, we are guaranteed to have at least 500 pouches retained. For this configuration, the 2 extra cases from the partially-filled pallet will provide an additional 48 pouches. If the cases are equally divided between two partial pallets, there would be 64 per pallet and the plan would still provide at least 500 pouches.

Consider an SKU date with 114942 pouches of a 3-ounce product with 24 pouches per case. The total number of cases is  $114942/24=4789.25$ , which we round down to 4789. For this product there are 160 cases per pallet, so there are  $4789/160=29.9$  pallets, which we round down to 29. The retrieval plan states that 1 case will be retained per pallet. If there are 29 full pallets, 160 cases per pallet and the remaining 149 cases are on another pallet, we will select a total of 30 cases, one from each pallet. The total number of pouches selected is  $30 \text{ pallets} \times 1 \text{ case per pallet} \times 24 \text{ pouches per case} = 720$  pouches, well in excess of our target of 500 pouches. If there is more than one partial pallet for this SKU date, then the number of cases retrieved will be greater as will the number of pouches retrieved.

This retrieval plan is based on an assumption that pallets will be examined one at a time. The SKU date will be determined and an index will be consulted to determine the number of cases to be selected. For situations where there is a list of pallets with pallet identifiers and the actual number of cases on each pallet, the same general principles are applied to determine the number of cases to be retrieved from each pallet. In the first example above, if we could identify the two pallets with 126 and 2 cases respectively, we would retrieve 2 cases from the partial pallet and the remainder of 19 cases from the full pallet for a total of 21 retained cases.

14. I next considered how cases should be selected from each pallet. I have concluded that cases should always be selected from the top of the pallets for the following reasons: (a) because of the way product is produced, cases within a pallet are expected to be very homogeneous, so a case selected from the top of a pallet is likely to be very similar to a randomly selected case from the pallet; (b) by selecting cases from all available pallets, we will be able to estimate the greatest source of variation, if any, which is pallet to pallet variation; (c) it is safer than random selection for the workers who will retrieve the cases; and (d) the time considerations of breaking down each pallet is excessive and unnecessary.

15. It is impractical, unsafe and unnecessary to require random sampling of cases within pallets. In response to my request for information regarding the time required for sampling cases from pallets in different ways, Tom Robinson of Iams provided me with the results of a study performed to assess the times required for (a) a procedure where a pallet is retrieved, cut at the top, one or more cases are removed from the top, the pallet is resealed and discarded; and (b) a procedure where a pallet is retrieved, unwrapped, one or more randomly selected cases are removed from within the pallet, the pallet is resealed and discarded. Mr.

Robinson indicated that procedure (a) would take about 3 minutes whereas procedure (b) would take much longer, i.e., 45 minutes. I understand Defendants would not be able to logically break down more than 4 pallets at a time even if dedicated manpower were not an issue. This means that if Iams were to break down each pallet for random retrieval assuming dedicated manpower working consistently 8 hours per day, it would take Iams 515 days to break down its 5,500 pallets. If it is able to logically break down 4 pallets at a time, it would take 125 days, over 4 months of dedicated labor, to execute the plan. By contrast, the time and cost necessary to remove cases from the top of the pallet is estimated at 15 times less per pallet, or 35 days to open all pallets (9 days if 4 pallets at a time).

16. There are also safety concerns with breaking down each pallet. I spoke with Menu personnel about breaking down pallets for random retrieval. I understand that Menu Foods is unable to safely retrieve a case from the sides of a pallet. There is a risk that the cases above will break and/or fall. Therefore, the only safe way to retrieve a case from a pallet is either to remove cases only from the top, or to completely break down the pallet (i.e., the time consuming process described above).

17. When product from the saved units is assayed, the results will be combined to estimate ranges of contamination for each SKU date. Strictly speaking, the inference will be restricted to the population of product that is currently being stored. Inference to product that is not currently being stored would be based on an assumption that the currently stored product is essentially the same as product not currently being stored.

18. Several technical considerations have led me to conclude that the true margins of error for our estimates will be less than those I calculated under the ideal framework

of simple random sampling. First, as noted above, by sampling all pallets, we will be able to estimate the dominant component of the variation very effectively. Second, by sampling cases from the top of each pallet, we are using a type of systematic sampling where the production process is sampled at equally spaced time points throughout the production process. This decision should result in smaller margins of error than simple random sampling. Third, the calculation of the expected margins of errors for the ranges of contamination on each SKU date involves the combination of two sources of variation, variation in the estimate of the mean and variation in the estimate of the standard deviation. With regard to the second source, we should be able to combine information from different SKU dates to produce more efficient estimates of the standard deviations, thereby essentially eliminating this source of variation. This will reduce the margins of error by approximately 42%. Note that for SKU dates with only one pallet, we will need to use information from other SKU dates to obtain an estimate of the standard deviation that accounts for pallet-to-pallet variation. Finally, if we view the population as all product produced on a given SKU date, available for retrieval or not, in many cases we will be sampling an appreciable fraction of the product produced at the level where we expect the most variation. A consequence is that the application of finite population corrections would result in smaller margins of error.

19. Based on my extensive review and analysis of the recalled product stored by each Defendant, the manner of storage by each Defendant, the production processes relevant to the recalled product and the practical considerations of breaking down each pallet, I have prepared retrieval plans for each Defendant. The retrieval plans for each Defendant's organized recalled product are attached as Exhibit 1 (Iams), Exhibit 2 (Hill's), Exhibit 3 (Nutro), Exhibit 4 (Purina), Exhibit 5 (Del Monte), and Exhibit 6 (Menu Foods). The variable, selectcasesperpallet,

specifies the number of cases per pallet to be retrieved. If a pallet has fewer than this number of cases, then all cases will be selected.

20. In my opinion, the retrieval plans and opinions that I set forth here for each Defendant are more than sufficient for estimating contamination, if any, for the SKU dates listed to a reasonable degree of scientific certainty. The following table summarizes by company the number of SKU dates, units currently stored, cases currently stored, units to be selected and cases to be selected. There are 1,732,595 units in 94,093 cases that will be selected for retrieval and retention. There are a total of 2,518 SKU dates for all Defendants.

<u>Company</u>	<u>SKU Dates</u>	<u>Units</u>	<u>Cases</u>	<u>Selected Units</u>	<u>Selected Cases</u>
Del Monte	46	1,028,138	115,913	30,194	3,360
Hill's	12	672,024	28,001	7,464	311
Iams	367	18,478,698	593,293	302,928	12,140
Menu Foods	2,007	50,986,940	2,471,016	1,300,081	73,834
Nestle Purina	64	4,845,764	229,942	64,284	3,121
Nutro	<u>82</u>	<u>95,533</u>	<u>4,588</u>	<u>27,644</u>	<u>1,327</u>
<b>Totals</b>	<b><u>2,578</u></b>	<b><u>76,107,097</u></b>	<b><u>3,442,753</u></b>	<b><u>1,732,595</u></b>	<b><u>94,093</u></b>

21. In addition to the SKU dates and units described in paragraph 20 above, Hill's has three SKU dates with bags rather than cans of product. This is product produced similarly to the Menu Foods production processes described above, and the same principles apply -- i.e., each batch fills many pallets, the process is fast, sequential and continuous, and the processes are designed for uniform production. However, because this product is stored in large bags (four or ten pounds each) on pallets, as opposed to cases containing several units, a separate

retrieval plan is necessary. For these three Hill's SKU dates, my plan provides for at least one bag to be taken from each pallet, and a total of 125 or more bags to be retrieved for each SKU date using the same retrieval methods described above. This means that four samples would be taken from each bag to achieve the 500 units recommended by my Sampling Plan. Hill's has a total of 6638 bags -- 975 four-pound bags and 5663 ten-pound bags -- on these three SKU dates. My retrieval plan calls for 461 bags to be retrieved. In my opinion, this retrieval plan is more than sufficient for estimating contamination, if any, for the SKU dates listed, to a reasonable degree of scientific certainty.

22. Finally, the opinions expressed in this Declaration are my own, and do not reflect those of Purdue University.

George P. McCabe  
George P. McCabe

Sworn to and subscribed in my presence by the said George P. McCabe, this  
26 day of March 2008.

Sally J. Goek  
Notary Public

"OFFICIAL SEAL"  
SALLY J. GOEKE  
Notary Public, State of Indiana  
My Commission Expires Aug. 7, 2014

My Commission expires: 8/7/14